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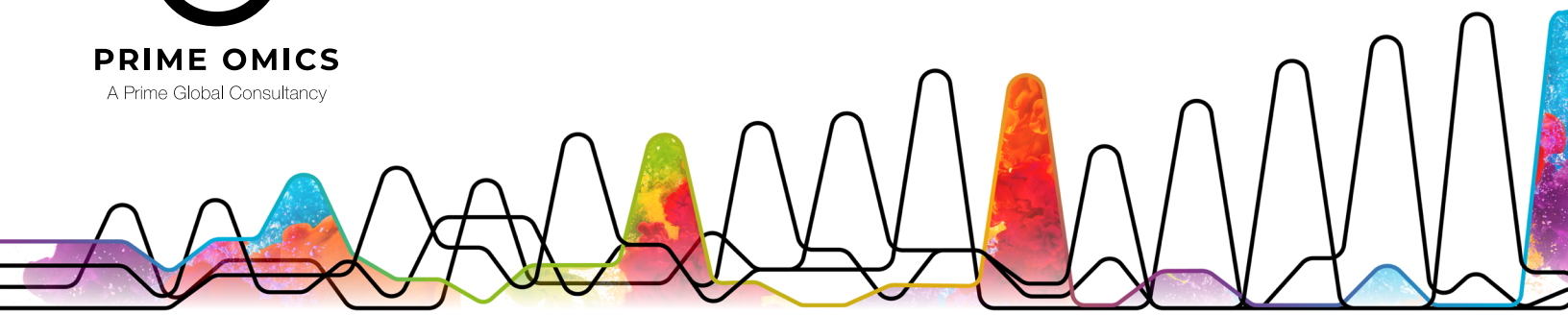

The future of precision medicine beyond oncology

Introduction

Over the past 20 years, molecular profiling has driven major advances in understanding the biology that drives cancer development.[1] As a result of these discoveries, cancer is no longer considered to be a single disease, and for some cancer types a one size fits all approach to treatment is becoming obsolete. Our growing knowledge of how to use biomarker profiling to target particular disease characteristics has created an alternative treatment approach. This is also known as 'Precision medicine: the right patient, the right treatment, at the right time'. Once a buzz phrase, precision medicine is now an integral part of healthcare systems for cancer treatment and beyond.[2]

Molecular profiling

The ability to profile complex molecular characteristics, such as gene sequence data, gene expression profiles, and immune repertoires, as well as the capability to develop novel therapeutic approaches, has been driven by the evolution of increasingly sophisticated molecular methods, such as next-generation sequencing.[3] As a result, and like no time before, healthcare systems are engaging with and practising medicine differently. Across a number of therapeutic areas there are increasing opportunities and challenges for utilising molecular profiling to predict disease risk, diagnose and characterise disease, monitor disease progression, and assess response to treatment.[2, 4, 5]

Example: inflammatory bowel disease (IBD)

Immunological diseases such as IBD are key therapeutic targets for precision medicine, as the complexity of biological determinants underlying the pathophysiology of these diseases is on a similar scale to that of cancer.[4] The pathogenesis of IBD can depend on genetic and environmental factors, with variation in the microbiome and immunome contributing to development of disease and its persistence. For these reasons, multi-omic biomarker profiling is being adopted by a number of pharma companies to derive a better understanding of the pathophysiology of IBD, and ultimately improve treatment outcomes for patients.[2, 4, 5] However, tailored health education may be needed to engage HCPs and patients and improve participation.[6]

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OPPORTUNITIES

Genetic testing
Genetic tests are now available for more than 17,000 human conditions across multiple organ systems.[7] These tests will allow HCPs to practise precision medicine, leading to better outcomes for patients.

Digital data exchange
The COVID-19 pandemic accelerated the need for the exchange of data without the restrictions of location.[11] As we enter the era of digital pathology, unrestricted online access to scientific data and preprint servers is becoming increasingly common, with researchers and publishers committed to their exchange.[12]

Targeted treatments
Individualised treatments that target specific disease characteristics can deliver improved efficacy and may offer more favourable safety profiles than traditional therapeutics, which will help improve adherence and outcomes.[14, 15]

Diseases beyond oncology
Precision medicine is facilitating change in the development of targeted, effective treatments for a large number of patients across a wide spectrum of diseases. Several pharma and biotech companies have adopted a precision-medicine approach to drive advances in disease research and drug development for the treatment of infectious, cardiovascular, renal, metabolic, respiratory, and immunological diseases.[2, 5, 17–20]

CHALLENGES

Diagnostic assay development
For complex molecular profiling, robust analysis from limited biological material can be challenging.[8] Precise and accurate interdisciplinary communication between assay developers and HCPs, global standardisation of assay outputs, and rigorous clinical validation of the diagnostic platform are critical for both a successful market adoption with HCPs and optimal payer engagement.[8–10]

Handling 'big data'
Radical changes in the infrastructure of pathological testing, including the adoption of digital platforms and machine-learning algorithms, may be required to handle and exchange 'big data' outputs.[13] Distinguishing accurate predictive values for precision treatments from technical noise, along with adapting and translating data outputs into key scientific communication points that are tailored for specific audiences, is important for building trust.[13]

Clinical validation
Prospective validation of the clinical efficacy of each precision treatment option is particularly challenging, as increasingly complex and stringent biomarker requirements can reduce the number of patients available for each clinical trial cohort.[16] As a result, robust reporting of biomarker and clinical data is key to building confidence in the market.

Education and awareness
Up-to-date communications on the ever evolving technology, and its applications, are critical to encourage engagement of both patients and HCPs, and to improve patient access to diagnosis and treatment options.[10]

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Prime Omics *is a specialist consultancy delivering technical and strategic support for the communication of omic-based data analyses. Prime Omics can help to bridge communication gaps between assay developers, biopharma, and a range of audiences from specialist HCPs to patients.*

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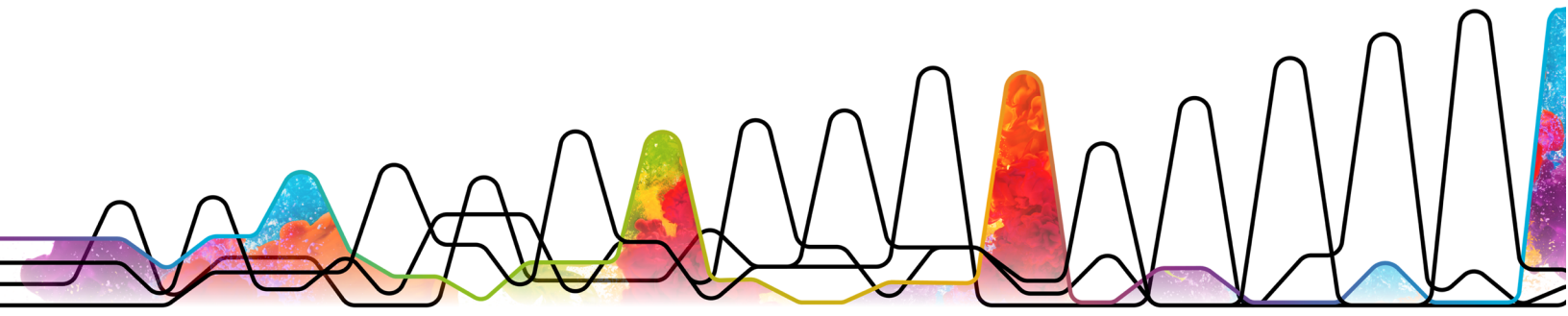

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